8/13 (AF) 1600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant (s): **Keith P. Johnston, et al.**

Serial No.: **09/808,332** Group Art Unit: **1615**

Filed: **March 14, 2001** Examiner: **Unknown**

For: **PREPARATION OF DRUG PARTICLES USING EVAPORATION PRECIPITATION INTO AQUEOUS SOLUTIONS**

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL WITH SUFFICIENT POSTAGE IN AN ENVELOPE ADDRESSED TO: ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, ON:

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February 28, 2003
DATE OF SIGNATURE

Bet 3-13-03

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO FINAL OFFICE ACTION

Introductory Comments

In response to the Official Action, mailed on December 30, 2002, Applicants respectfully request that the above identified application be reconsidered in view of the amendments and remarks included herewith.

Amendments to the Claims

Amendments to the Claims are presented in the pages submitted herewith. Claims 1, 27 and 28 are currently amended. Claims 2 and 3 have been canceled.

Support for the amendments to Claims 1, 27 and 28 to point out that at least one particle stabilizer is originally present in the aqueous solution, the drug/organic mixture or both the aqueous solution and the drug/organic mixture is supported by Claim 2 as originally filed. Support for the amendments to Claims 1, 27 and 28 stating that the stabilizer covers the drug particles as the organic solvent is evaporated is supported by the specification at page 7 lines 23-24. No new matter is presented with the above amendments.

Remarks

Applicants would like to thank the Examiner for the recent interview regarding the present application.

Response to the Rejections under 35 USC 103

The Examiner rejected Claims 1-28 under 35 USC 103(a) as being unpatentable over US Patent 5,985,248 to Gordon. Amended Claims 1, 27 and 28 recite, in part, the step of spraying a drug/organic mixture into an aqueous solution, wherein at least one particle stabilizer is originally present in the aqueous solution, the drug/organic mixture or both the aqueous solution and the drug/organic mixture, and wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution. Gordon does not teach or suggest spraying the drug/organic mixture into an aqueous solution at or below the liquid level of the aqueous solution.

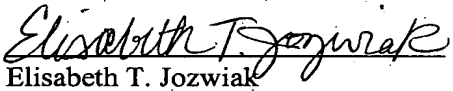
In the Official Action of December 30, 2002, the Examiner invited Applicants to point out the significance of spraying below the liquid level of the aqueous solution. As discussed during the recent interview and as described in the specification of the present application on page 7 lines 23-24, spraying below the liquid level of the aqueous solution permits evaporation of the solvent while the water remains behind, such that the stabilizers remain solvated by the water even as the organic solvent is evaporated. As described on page 2 lines 7-8 of the specification, solvation of the stabilizer is necessary for it to be able to prevent growth of the drug particles. The resulting product has a relatively small particle size.

By contrast, in Gordon, spraying into vapor causes the water to evaporate together with the organic solvent. As a result, the water is not left behind to solvate the stabilizer, so the stabilizer will not be as effective at inhibiting particle growth. As a result, the particle size of the product produced by the Gordon process would be larger than that using the process of the present application. The amendments presented in this response are for the purpose of clarifying this distinction over Gordon.

Conclusion

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration of the application.

Respectfully submitted,



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